UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

# NOTICE OF ALLOWANCE AND FEE(S) DUE

26164

7590

07/07/2008

FISH & RICHARDSON P.C. P.O BOX 1022 MINNEAPOLIS, MN 55440-1022 EXAMINER

ANDERSON, REBECCA L

ART UNIT PAPER NUMBER

1626

DATE MAILED: 07/07/2008

| APPLICATION NO.                  | FILING DATE      | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.    | CONFIRMATION NO. |
|----------------------------------|------------------|----------------------|------------------------|------------------|
| 10/542,044                       | 07/13/2005       | Andrew David Morley  | 06275-460US1 100928-1P | 8677             |
| THE PARTY OF THE PROPERTY OF THE | HODIENE GARRONAR | US                   |                        |                  |

TITLE OF INVENTION: THIOPHENE CARBOXANMIDES AS INHIBITORS OF THE ENZYME IKK-2

| APPLN. TYPE    | SMALL ENTITY | ISSUE FEE DUE | PUBLICATION FEE DUE | PREV. PAID ISSUE FEE | TOTAL FEE(S) DUE | DATE DUE   |
|----------------|--------------|---------------|---------------------|----------------------|------------------|------------|
| nonprovisional | NO           | \$1440        | \$300               | \$0                  | \$1740           | 10/07/2008 |

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

#### HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

### PART B - FEE(S) TRANSMITTAL

### Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE

Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

or <u>Fax</u> (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where

| appropriate. All further<br>indicated unless correcte<br>maintenance fee notificate   | correspondence including<br>ed below or directed other<br>tions   | ng the Patent, advance on<br>nerwise in Block 1, by (a                       | rders and notification of r<br>a) specifying a new corres   | naintenance fees was pondence address;   | ill be<br>and/or           | mailed to the current<br>(b) indicating a sepa                             | correspondence address as<br>urate "FEE ADDRESS" for  |
|---|---|--|---|--|----------------------------|--|---|
| CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)  |   |  |   | (s) Transmittal. Thi<br>ers. Each additiona  | s certif<br>I paper        | icate cannot be used f   | or domestic mailings of the<br>for any other accompanying<br>ant or formal drawing, must  |
| FISH & RICHA<br>P.O BOX 1022<br>MINNEAPOLIS   |   | /2008  |   | Cor  | tificate                   | of Mailing or Trans  | mission g deposited with the United st class mail in an envelope above, or being facsimile ate indicated below.                         |
|   |   |  |   |  |                            |  | (Depositor's name)  |
|   |   |  |   |  |                            |  | (Signature)   |
|   |   |  |   |  |                            |  | (Date)  |
| APPLICATION NO.   | PLICATION NO. FILING DATE   |  | FIRST NAMED INVENTOR  | NVENTOR  |                            | RNEY DOCKET NO.  | CONFIRMATION NO.  |
| 10/542,044  | 07/13/2005  |  | Andrew David Morley   |  | 06275-                     | 460US1 100928-1P<br>US   | 8677  |
|   |   |  | TORS OF THE ENZYME  |  | 2 1700                     | TOTAL EFF(0) DUE   | DATE DIE  |
| APPLN. TYPE   | SMALL ENTITY  | ISSUE FEE DUE  | PUBLICATION FEE DUE   | PREV. PAID ISSUE   | S FEE                      | TOTAL FEE(S) DUE   | DATE DUE  |
| nonprovisional  | NO  | \$1440   | \$300   | \$0<br><b>1</b>  |                            | \$1740   | 10/07/2008  |
| EXAM  |   | ART UNIT   | CLASS-SUBCLASS  | ]  |                            |  |   |
| ANDERSON,   |   | 1626   | 514-445000  2. For printing on the p  |  |                            |  |   |
| <ul> <li>1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).</li> <li>1. Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.</li> <li>1. "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Customer Number is required.</li> </ul> |   |  | (1) the names of up to<br>or agents OR, alternati<br>(2) the name of a singl<br>registered attorney or a<br>2 registered patent atto<br>listed, no name will be | the names of up to 3 registered patent attorneys gents OR, alternatively,  the name of a single firm (having as a member a stered attorney or agent) and the names of up to gistered patent attorneys or agents. If no name is d, no name will be printed. |                            |  |   |
| PLEASE NOTE: Unl<br>recordation as set forti<br>(A) NAME OF ASSIG   | less an assignee is ident<br>h in 37 CFR 3.11. Comp<br>GNEE   | ified below, no assignee<br>oletion of this form is NO                       | (B) RESIDENCE: (CITY  | atent. If an assign<br>assignment.<br>'and STATE OR C  | OUNT                       | RY)  | ocument has been filed for  |
| Please check the appropr  | iate assignee category or   | categories (will not be pr   | rinted on the patent):  | Individual 🖵 Co  | rporati                    | on or other private gro  | oup entity Government   |
| 4a. The following fee(s) are submitted:  ☐ Issue Fee ☐ Publication Fee (No small entity discount permitted) ☐ Advance Order - # of Copies   |   |  | <ul> <li>Payment of Fee(s): (Plea</li> <li>A check is enclosed.</li> <li>Payment by credit car</li> <li>The Director is hereby overpayment, to Depo</li> </ul>  | d. Form PTO-2038 v authorized to char  | is atta                    | ched.<br>required fee(s), any de   |   |
|   | <b>tus</b> (from status indicateds<br>s SMALL ENTITY state  |  | ☐ b. Applicant is no lon  | aan alaimina SMAI  | I DN                       | FITV status See 27 CI  | ED 1.27(~)(2)   |
|   |   |  |   |  |                            |  | ne assignee or other party in   |
| Authorized Signature  |   |  |   | Date   |                            |  |   |
| Typed or printed name   |   |  |   | Registration N   | o                          |  |   |
| an application. Confident<br>submitting the completed<br>his form and/or suggesti   | tiality is governed by 35<br>d application form to the<br>ions for reducing this but<br>firginia 22313-1450. DC | U.S.C. 122 and 37 CFR<br>USPTO. Time will vary<br>rden, should be sent to th | 1.14. This collection is est depending upon the indiverse Chief Information Office  | imated to take 12 r<br>ridual case. Any co<br>er. U.S. Patent and  | ninutes<br>mment<br>Traden | to complete, including<br>s on the amount of time<br>ark Office, U.S. Depa | I by the USPTO to process) gg athering, preparing, and me you require to complete artment of Commerce, P.O. for Patents, P.O. Box 1450, |

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.



### United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

| APPLICATION NO.            | FILING DATE    | FIRST NAMED INVENTOR   | ATTORNEY DOCKET NO.    | CONFIRMATION NO. |  |
|----------------------------|----------------|------------------------|------------------------|------------------|--|
| 10/542,044                 | 07/13/2005     | Andrew David Morley    | 06275-460US1 100928-1P | 8677             |  |
| 26164 75                   | 590 07/07/2008 |                        | EXAM                   | INER             |  |
| FISH & RICHARDSON P.C.     |                |                        | ANDERSON, REBECCA L    |                  |  |
| P.O BOX 1022               |                |                        | ART UNIT               | PAPER NUMBER     |  |
| MINNEAPOLIS, MN 55440-1022 |                |                        | 1626                   |                  |  |
|                            |                | DATE MAILED: 07/07/200 | 8                      |                  |  |

## **Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)**

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 88 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 88 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 (571)-272-4200.

|   | Application No.  | Applicant(s)  |
|---|--|---|
|   | 10/542,044   | MORLEY ET AL.   |
| Notice of Allowability  | Examiner   | Art Unit  |
|   | REBECCA L. ANDERSON  | 1626  |
|   | REBECCA L. ANDERSON  | 1626  |
| The MAILING DATE of this communication apperall claims being allowable, PROSECUTION ON THE MERITS IS herewith (or previously mailed), a Notice of Allowance (PTOL-85) NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT R of the Office or upon petition by the applicant. See 37 CFR 1.313 | (OR REMAINS) CLOSED in this ap<br>or other appropriate communication<br>IGHTS. This application is subject | oplication. If not included n will be mailed in due course. <b>THIS</b> |
| 1. $\boxtimes$ This communication is responsive to <u>the amendment filed</u>   | 14 April 2008.   |   |
| 2. ☑ The allowed claim(s) is/are <u>1-3, 5-10 and 13-15</u> .   |  |   |
| 3. Acknowledgment is made of a claim for foreign priority under a) All b) Some* c) None of the:   |  |   |
| 1. Certified copies of the priority documents have  |  |   |
| 2. Certified copies of the priority documents have  | •  |   |
| 3. Copies of the certified copies of the priority do  | cuments have been received in this   | national stage application from the                                     |
| International Bureau (PCT Rule 17.2(a)).  |  |   |
| * Certified copies not received:  |  |   |
| Applicant has THREE MONTHS FROM THE "MAILING DATE" noted below. Failure to timely comply will result in ABANDONN THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.   |  | complying with the requirements   |
| 4. A SUBSTITUTE OATH OR DECLARATION must be subm<br>INFORMAL PATENT APPLICATION (PTO-152) which give  |  |   |
| 5. CORRECTED DRAWINGS ( as "replacement sheets") mus  | st be submitted.   |   |
| (a) including changes required by the Notice of Draftspers  | son's Patent Drawing Review(PTC  | 9-948) attached   |
| 1) 🗌 hereto or 2) 🔲 to Paper No./Mail Date  |  |   |
| (b) ☐ including changes required by the attached Examiner'<br>Paper No./Mail Date   | s Amendment / Comment or in the  | Office action of  |
| Identifying indicia such as the application number (see 37 CFR 1 each sheet. Replacement sheet(s) should be labeled as such in t  |  |   |
| <ol> <li>DEPOSIT OF and/or INFORMATION about the depo-<br/>attached Examiner's comment regarding REQUIREMENT</li> </ol>   |  |   |
|   |  |   |
| Attachment(s) 1. ☑ Notice of References Cited (PTO-892)   | 5.   | Patent Application  |
| Notice of Neterlances Cited (F10-032)     Notice of Draftperson's Patent Drawing Review (PTO-948)   | 6. ☐ Interview Summar  |   |
| 3. ☐ Information Disclosure Statements (PTO/SB/08),   | Paper No./Mail Da<br>7. ☐ Examiner's Amend   | ate   |
| Paper No./Mail Date  4.  Examiner's Comment Regarding Requirement for Deposit   |  | nent of Reasons for Allowance   |
| of Biological Material  | 9.   |   |
|   | o. 🗀 outor   |   |
|   |  |   |
|   |  |   |

Application/Control Number: 10/542,044 Page 2

Art Unit: 1626

### **DETAILED ACTION**

Claims 1-3, 5-10 and 13-15 are currently pending in the instant application, appear allowable over the prior art of record and have been renumbered as claims 1-12.

## Response to Amendment and Arguments

Applicants' amendment and arguments filed 14 April 2008 have been fully considered and entered into the instant application. Applicants' amendment has overcome the objection to claim 13 for informalities. Applicants' amendment of claim 13 and the cancellation of claim 17 along with applicants' arguments and the state of the art at the time of applicants' invention as seen in WO 200246171 has overcome the 35 USC 112 1st paragraph rejection.

#### Reasons for Allowance

The following is an examiner's statement of reasons for allowance. This invention relates to products of the formula (I), processes of preparation and methods of treating inflammatory disorders selected from asthma, rheumatoid arthritis, multiple sclerosis and chronic obstructive pulmonary disease. The novel and nonobvious aspect of this invention involves the products of the formula (I). The closest prior art of record fails to teach or suggest Applicants' instantly claimed formula (I). Additionally, as can be seen by WO 200246171, NF- kB has a central role in inflammatory disease(page 1) and cell and animal experiments indicate that IKK-2 is a central regulator of the pro-inflammatory role of NF-kB and is activated in response to multiple inflammatory stimula and signaling pathways, page 3.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

#### Conclusion

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rebecca L. Anderson whose telephone number is (571) 272-0696. Mrs. Anderson can normally be reached Monday through Friday from 6:00am until 2:30pm.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Joseph K. McKane, can be reached at (571) 272-0699.

Art Unit: 1626

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rebecca Anderson/ Primary Examiner, AU 1626

Rebecca Anderson Primary Examiner Art Unit 1626, Group 1620 Technology Center 1600 1 July 2008